

REMARKS

Favorable reconsideration and allowance of the claims of the present application are respectfully requested.

Before addressing the rejections raised in the Official Action, Applicants have amended claims in a manner shown above. Support for the amendments to the claims are found at pages 7, 12 and 15 of the originally filed specification; and the originally filed Claims 1-14. Since the above amendments to the claims do not introduce any new matter into the application, entry thereof is respectfully requested.

In the Official Action, Claims 5-14 are objected to as allegedly in improper form because a multiple dependent claim cannot depend on a multiple dependent claim. Moreover, Claims 1-14 are rejected under 35 U.S.C. §101 on the ground that these claims are directed to a use and fail to set forth any steps involved in a process. Furthermore, Claims 1-14 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite on the ground that the use claims fail to set forth any steps involved in the process.

In response, Applicants submit that the instant objection and rejections have been obviated in view of the claims as presently amended. Specifically, Applicants have amended the pending claims to conform to the method of treatment format, and have also eliminated the multiple dependencies of the claims. Therefore, reconsideration and withdrawal of the instant objection and rejections is respectfully requested.

Further, Claims 1-14 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement in view of the term “prophylaxis” recited in Claim 1.

In response, applicants have deleted the term “prophylaxis” in Claim 1 without prejudice. In view of this amendment to Claim 1, Applicants submit that the instant §112, first paragraph rejection is obviated, and thus reconsideration and withdrawal of such rejection is respectfully requested.

In addition to the above-described rejections, Claims 1-3 and 7-12 are rejected under 35 U.S.C. §102 (b) as allegedly anticipated by U.S. Patent Application Publication No. 2002/0025361 to Kawachi et al. (“Kawachi et al.”). Specifically, the Examiner contends that Kawachi et al. inherently teach a composition comprising whey permeate in treating metabolic syndrome or type 2 diabetes or secondary diseases thereof.

In response, Applicants respectfully submit that Kawachi et al. merely disclose a composition (comprising whey permeate) which is highly dispersible and tasteful when mixed with a calcium-fortified drink or food product. See paragraphs [0002], [0006], [0007] and [0009] to [0012] at page 1. Moreover, Applicants observe that nowhere do Kawachi et al. teach or suggest utilizing whey permeate, as presently claimed, to treat metabolic syndrome or type 2 diabetes or secondary diseases thereof. Further, Applicants observe that there is no direct or indirect link between utilizing whey permeate to provide calcium and utilizing whey permeate to treat metabolic syndrome or type 2 diabetes or secondary diseases thereof. Therefore, Applicants submit that the Examiner has not met the requisite burden: the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Ex parte Levy, 17 USPQ2d 1461, 1464 (B.P.A.I. 1990) (Emphasis added).

In view of the foregoing, it is respectfully submitted that the rejection under 35 U.S.C. §102(b) based on Kawachi et al. is obviated. Withdrawal of the rejection is respectfully

requested.

Further, Claims 1-14 are rejected under 35 U.S.C. §103 (a) as allegedly obvious over Kawachi et al. in view of U.S. Patent No. 5,213,826 to Miller et al. ("Miller et al.").

The deficiencies of Kawachi are described above. Miller et al. fail to ameliorate the deficiencies of Kawachi et al. Specifically, Applicants observe that Miller et al. merely disclose providing whey permeate sweetener, which is used as a feed supplement or is combinable with other food components, to produce a more palatable feed for animals. See the abstract; lines 10-21 of column 1; column 2, line 65 to column 3, line 26 to column 4, line 4; and Claims 1-11 at columns 12-14. There is absolutely no recognition of treating the claimed disorders in the cited reference, and thus, no motivation to use whey permeate as claimed. Therefore, Applicants submit that Miller et al. do not teach or suggest using the whey permeate sweetener in the treatment of metabolic syndrome or type 2 diabetes or secondary diseases thereof. As such, Applicants submit that the combination of Kawachi et al. and Miller et al. does not render the present claims obvious.

In view of the foregoing, it is respectfully submitted that the rejection under 35 U.S.C. §103 (a) based on Kawachi et al. in view of Miller et al. is obviated. Withdrawal of the rejection is respectfully requested.

Further, Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly obvious over Claims 12-14 of the copending U.S. Patent Application No.12/376,146.

In response, Applicants respectfully submit that since the claims in the present application and the copending application may be amended to a great extent during the prosecution process, it is inappropriate and premature to impose the rejection at present. An

appropriate terminal disclaimer may be filed upon the allowance of the relevant claims. In view of the foregoing, it is respectfully submitted that the nonstatutory obviousness-type double patenting rejection is obviated. Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Frank S. DiGiglio', written over the printed name.

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